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14 Counterclaimant ABBOTT
CARDIOVASCULAR SYSTEMS, INC.

15 UNITED STATES DISTRICT COURT
16 CENTRAL DISTRICT OF CALIFORNIA

17 EDWARDS LIFESCIENCES
18 CORPORATION, a Delaware
corporation and EDWARDS
19 LIFESCIENCES LLC, a Delaware
corporation

20 Plaintiff,

21 v.

22 ABBOTT CARDIOVASCULAR
23 SYSTEMS, INC., a California
corporation,

24 Defendant.

CASE NO. 8:19-cv-00345-JLS-JDE

**DEFENDANT ABBOTT
CARDIOVASCULAR SYSTEM INC.'S
ANSWER, DEFENSES, AND
COUNTERCLAIMS**

DEMAND FOR JURY TRIAL

PRELIMINARY STATEMENT

Plaintiffs Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively, “Edwards”) filed this Complaint more than 15 years *after* the earliest of its asserted patents issued and more than a decade *after* Defendant Abbott Cardiovascular Systems, Inc. (“Abbott”) began manufacturing its pioneering MitraClip® device in the United States. If Abbott truly infringed Edwards’s patents, Edwards would have filed suit more than a decade ago. Its failure to do so is explained by one simple fact: ***Abbott does not infringe Edwards’s patents.***

So why now, after all these years? One reason: in retaliation to Abbott’s recently-filed action in Delaware, which seeks to enjoin Edwards from infringing multiple Abbott patents that cover the same MitraClip products that Edwards accuses in this case.¹

Abbott’s innovative, patent-protected MitraClip treats mitral regurgitation (“MR”), a heart condition that causes blood to flow backwards through the mitral valve. Abbott began developing MitraClip in the 1990s and had to overcome substantial hurdles to do so: implanting a device to capture two continuously moving leaflets in a beating heart presented enormous design, regulatory, doctor-training, and reimbursement challenges. MitraClip required the creation of an entirely new surgical procedure where none existed—percutaneous “edge-to-edge repair.”

Yet, Abbott persevered. MitraClip received “CE-Mark” approval for marketing in Europe in 2008, and FDA approval for marketing in the United States in 2013. The FDA recognized MitraClip as a “first-in-class device representing a

¹ See *Abbott Cardiovascular Sys., Inc., et al. v. Edwards Lifesciences Corp., et al.*, C.A. No. 19-149-MN, Dkt. 14 (Jan. 29, 2019) (“the Delaware Action”).

breakthrough technology” to treat life-threatening heart problems.² To this day, MitraClip is the only FDA-approved transcatheter-based mitral repair device in the United States. MitraClip is so groundbreaking that the New York Times touted MitraClip in a front-page article, in which doctors called MitraClip “a game changer” that permitted them to treat MR “in a way [they] never thought [they] could.”³

While Abbott was developing and commercializing this “game changer,” Edwards’s efforts at making a competing device floundered. For more than eight years in the 2000s, Edwards tried to develop a competing edge-to-edge leaflet repair device, called “Mobius.”⁴ But that effort failed due to, among other things, “poor intermediate durability results.”⁴ Edwards finally gave up in 2008 and suspended the development of Mobius because of “mixed results, procedural complexity, and a perceived limited patient population.”⁵ Mobius never reached the market.

More than a decade after abandoning Mobius, and following MitraClip’s unparalleled success, Edwards tried a new tack: emulate Abbott’s patented technology. The result is Edwards’s infringing PASCAL device, which Edwards

² Letter from Denise Hinton, Chief Scientist, FDA to Stephanie Philbin, Goodwin & Proctor LLP, Re: Citizen Petition for Due Diligence Determination of Patent Term Extension for MITRACLIP CDS; Docket Nos. FDA-2014-E-2358; FDA-2014-E-2359 (FDA RADM Chief Scientist Letter) at 7–8 (July 12, 2018) (denying petition).

³ Gina Kolata, *Tiny Device is a ‘Huge Advance’ for Treatment of Serious Heart Failure*, THE NEW YORK TIMES (Sept. 23, 2018), <https://www.nytimes.com/2018/09/23/health/heart-failure-valve-repair-microclip.html>.

⁴ Nocolo Piazza, et al., *Transcatheter Mitral and Pulmonary Valve Therapy*, J. AM. COLLEGE OF CARDIOLOGY. 53(20):1837-1851 at 1838-41 (2009); see also Michael J. Mack, *Percutaneous treatment of mitral regurgitation: So near, yet so far!*, J. OF THORACIC AND CARDIOVASCULAR SURGERY 135(3):238 (2008).

⁵ Michael J. Mack, *Percutaneous treatment of mitral regurgitation: So near, yet so far!*, J. OF THORACIC AND CARDIOVASCULAR SURGERY 135(3):238 at 238 (2008).

1 announced on February 19, 2019 has received CE-Mark approval to commercially
2 market in Europe.⁶

3 Abbott moved for a preliminary injunction to stop Edwards from making the
4 infringing PASCAL devices in the United States; that motion is pending in the
5 Delaware Action.⁷ This action, filed less than a month after that motion was filed,
6 should be seen for what it is: a baseless, retaliatory response by Edwards in which
7 it asserts inapplicable patents to try to level the playing field.

8 Abbott denies that it infringes, or has infringed, any valid claim of the
9 Asserted Patents, denies that there is any legitimate basis for the lawsuit brought
10 by Edwards, denies that Edwards is entitled to any relief, and denies the allegations
11 and characterizations of Edwards's Complaint unless expressly admitted in the
12 following paragraphs as follows:

13 **I. THE PARTIES**

14 1. Abbott admits that Edwards Lifesciences Corporation is a corporation
15 organized and existing under the laws of the State of Delaware, with its principal
16 place of business at One Edwards Way, Irvine, California.

17 2. Abbott is without knowledge or information sufficient to form a belief
18 as to the truth of the allegations of paragraph 2 and therefore denies them.

19 3. Abbott admits that Abbott Cardiovascular Systems, Inc. is a
20 corporation organized and existing under the laws of the state of California, with its
21 principal place of business at 3200 Lakeside Drive, Santa Clara, California.

22 4. Paragraph 4 contains Edwards's party name abbreviations used through
23 the Complaint. As this paragraph contains no allegations, no response is required.
24

25 _____
26 ⁶ *Edwards PASCAL Transcatheter Receives CE Mark* (Feb. 19, 2019),
<https://www.edwards.com/ns20190219>.

27 ⁷ *See Abbott Cardiovascular Sys., Inc., et al. v. Edwards Lifesciences Corp., et al.*,
28 C.A. No. 19-149-MN, Dkt. 10 (Jan. 29, 2019).

II. JURISDICTION AND VENUE

5. Abbott admits that the Complaint purports to be an action for patent infringement arising under the patent laws of the United States of America, Title 35, United States Code. Abbott admits that, if the standing requirements are met, this Court has subject matter jurisdiction over this action. Abbott denies that Edwards has established that it has standing to assert the claims set forth in this Complaint.

6. Abbott admits that Abbott markets, manufactures, and sells MitraClip[®], and/or has marketed and sold MitraClip[®] NT, MitraClip[®] NTR, and MitraClip[®] XTR in the United States, including within this District. Abbott also admits that Edwards's Complaint refers to MitraClip, MitraClip NT, MitraClip NTR, and MitraClip XTR collectively as the "Accused Products." Any remaining allegations of paragraph 6 are denied.

7. Paragraph 7 contains conclusions of law, and therefore no response is required. Moreover, Edwards's infringement allegations are wrong. The Accused Products do not practice the Asserted Patents and Abbott has committed no acts of infringement, in this District or otherwise.

8. Paragraph 8 contains conclusions of law, and therefore no response is required. Moreover, Abbott has committed no acts of infringement, in this District or otherwise.

III. THE PATENTS-IN-SUIT

9. Abbott admits that what purports to be a copy of U.S. Patent No. 6,719,767 (the "'767 Patent") is attached to the Complaint as Exhibit 1 and that the face of the patent bears an issuance date of April 13, 2004 and the title "Device and a Method for Treatment of Atrioventricular Regurgitation." Abbott is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 9 and therefore denies them.

10. Abbott is without knowledge or information sufficient to form a belief

as to the truth of the allegations of paragraph 10 and therefore denies them.

11. Abbott admits that what purports to be a copy of U.S. Patent No. 7,011,669 (the “’669 Patent”) is attached to the Complaint as Exhibit 2 and that the face of the patent bears an issuance date of March 14, 2006 and the title “Device and a Method for Treatment of Atrioventricular Regurgitation.” Abbott is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 11 and therefore denies them.

12. Abbott is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 12 and therefore denies them.

13. Abbott admits that what purports to be a copy of U.S. Patent No. 8,062,313 (the “’313 Patent”) is attached to the Complaint as Exhibit 3 and that the face of the patent bears an issuance date of November 22, 2011 and the title “Device and a Method for Treatment of Atrioventricular Regurgitation.” Abbott is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 13 and therefore denies them.

14. Abbott is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14 and therefore denies them.

15. Abbott admits that Edwards’s Complaint refers collectively to the ’767 Patent, the ’669 Patent, and the ’313 Patent as the “Asserted Patents.”

IV. COUNT 1 – ALLEGED INFRINGEMENT OF THE ’767 PATENT

16. Paragraph 16 incorporates by reference paragraphs 1 through 15 and does not require a response. Abbott incorporates by reference its responses to paragraphs 1 through 15 as if fully set forth herein.

17. Abbott admits that Abbott markets, manufactures, and sells, and/or has marketed and sold, the Accused Products in the United States, including in this District. Abbott denies that such products infringe any valid claim of the ’767 Patent. Any remaining allegations of paragraph 17 are denied.

18. Denied.

19. Abbott admits that Exhibit 4 of Edwards's Complaint purports to be a claim chart comparing claim 14 to the Accused Products. Any remaining allegations of paragraph 19 are denied.

20. Abbott admits that MitraClip is delivered to a beating heart through a minimally invasive procedure that uses a catheter and a clip delivery system. Abbott also admits that MitraClip has Instructions for Use in compliance with the U.S. Food & Drug Administration ("FDA") requirements. Any remaining allegations of paragraph 20 are denied.

21. Denied.

22. Denied.

23. Paragraph 23 contains a conclusion of law that requires no response. Abbott admits that the '767 Patent was cited by Abbott's counsel in an information disclosure statement to the United States Patent and Trademark Office ("PTO") during the prosecution of U.S. Patent No. 7,335,213. Abbott denies that it engaged in, or had any actual knowledge of, any alleged infringement of the '767 Patent, whether before the filing of the Complaint or after. In fact, in the years the Accused Products were on the market before the filing of the Complaint, Plaintiff never notified Abbott of any such alleged infringement. Any remaining allegations of paragraph 23 are denied.

24. Denied.

V. COUNT 2 – ALLEGED INFRINGEMENT OF THE '669 PATENT

25. Paragraph 25 incorporates by reference paragraphs 1 through 24 and does not require a response. Abbott incorporates by reference its responses to paragraphs 1 through 24 as if fully set forth herein.

26. Denied.

27. Denied.

1 28. Abbott admits that Exhibit 5 purports to be Instructions for Use for
2 MitraClip®. Any remaining allegations of paragraph 28 are denied.

3 29. Abbott admits that Exhibit 6 of Edwards's Complaint purports to be a
4 claim chart comparing claim 1 of the '669 Patent to the Accused Products. Any
5 remaining allegations of paragraph 29 are denied.

6 30. Denied.

7 31. Denied.

8 32. Paragraph 32 contains a conclusion of law that requires no response.
9 Abbott admits that the '669 Patent was cited by Abbott's counsel in an information
10 disclosure statement to the PTO during the prosecution of U.S. Patent No.
11 10,188,392. Abbott denies that it engaged in, or had any actual knowledge of, any
12 alleged infringement of the '669 Patent, whether before the filing of the Complaint
13 or after. In fact, in the years the Accused Products were on the market before the
14 filing of the Complaint, Plaintiff never notified Abbott of any such alleged
15 infringement. Any remaining allegations of paragraph 32 are denied.

16 33. Denied.

17 **VI. COUNT 3 – ALLEGED INFRINGEMENT OF THE '313 PATENT**

18 34. Paragraph 34 incorporates by reference paragraphs 1 through 33 and
19 does not require a response. Abbott incorporates by reference its responses to
20 paragraphs 1 through 33 as if fully set forth herein.

21 35. Abbott admits that Abbott markets, manufactures, and sells, and/or has
22 marketed and sold, the Accused Products in the United States, including in this
23 District. Abbott denies that such products infringe any valid claim of the '313
24 Patent. Any remaining allegations of paragraph 35 are denied.

25 36. Denied.

26 37. Abbott admits that Exhibit 7 of Edwards's Complaint purports to be a
27 claim chart comparing claim 1 of the '313 Patent to the Accused Products. Any
28

1 remaining allegations of paragraph 37 are denied.

2 38. Abbott admits that MitraClip is delivered to a beating heart through a
3 minimally invasive procedure that uses a catheter and a clip delivery system. Abbott
4 also admits that MitraClip has Instructions for Use in compliance with FDA
5 requirements. Any remaining allegations of paragraph 38 are denied.

6 39. Denied.

7 40. Denied.

8 41. Paragraph 41 contains a conclusion of law that requires no response.
9 Abbott admits that the '313 Patent was cited by Abbott's counsel in an information
10 disclosure statement to the PTO during the prosecution of U.S. Patent No.
11 10,188,392. Abbott denies that it engaged in, or had any actual knowledge of, any
12 alleged infringement of the '313 Patent, whether before the filing of the Complaint
13 or after. In fact, in the years the Accused Products were on the market before the
14 filing of the Complaint, Plaintiff never notified Abbott of any such alleged
15 infringement. Any remaining allegations of paragraph 41 are denied.

16 42. Denied.

17 **VII. EDWARDS'S PRAYER FOR RELIEF**

18 These paragraphs (43-50) set forth Edwards's prayer for relief to which no
19 response is required. To the extent that responses to these paragraphs are required,
20 Abbott denies any allegations set forth therein and denies that Edwards is entitled to
21 any relief.

22 **VIII. JURY DEMAND**

23 This paragraph sets forth Edwards's request for trial by jury to which no
24 response is required.

25 **IX. DEFENSES**

26 Subject to the responses above, upon information and belief, Abbott alleges
27 and asserts at least the following defenses in response to Edwards's allegations,
28

1 undertaking the burden of proof only as to those defenses deemed affirmative
 2 defenses by law, regardless of how such defenses are named herein. In addition to
 3 the defenses described below, subject to the responses above, Abbott specifically
 4 reserves all rights to allege additional defenses that are not required to be pleaded or
 5 that become known through the course of discovery.

6 **FIRST DEFENSE**
 7 **(Non-Infringement)**

8 1. Abbott has not infringed and does not directly infringe any valid,
 9 enforceable, asserted claim of U.S. Patent No. 6,719,767 (“the ’767 Patent”), either
 10 literally or under the doctrine of equivalents, or under any theory of infringement.

11 2. Abbott has not infringed and does not directly or indirectly infringe any
 12 valid, enforceable, asserted claim of U.S. Patent No. 7,011,669 (“the ’669 Patent”),
 13 either literally or under the doctrine of equivalents, or under any theory of
 14 infringement.

15 3. Abbott has not infringed and does not directly infringe any valid,
 16 enforceable, asserted claim of U.S. Patent No. 8,062,313 (“the ’313 Patent”), either
 17 literally or under the doctrine of equivalents, or under any theory of infringement.

18 **SECOND DEFENSE**
 19 **(Invalidity)**

20 4. Each of the asserted claims of the ’767 Patent is invalid for failure to
 21 comply with one or more conditions of patentability set forth in 35 U.S.C. §§ 102,
 22 103, and/or 112.

23 5. Each of the asserted claims of the ’669 Patent is invalid for failure to
 24 comply with one or more conditions of patentability set forth in 35 U.S.C. §§ 102,
 25 103, and/or 112.

26 6. Each of the asserted claims of the ’313 Patent is invalid for failure to
 27
 28

1 comply with one or more conditions of patentability set forth in 35 U.S.C. §§ 102,
2 103, and/or 112.

3 **THIRD DEFENSE**
4 **(Prosecution History Disclaimer and Estoppel)**

5 7. Edwards is barred, based on statements, representations, and
6 admissions made during prosecution of the patent applications resulting in the
7 Asserted Patents or related patent applications, from asserting any interpretation of
8 any valid, enforceable claims of the Asserted Patents that would be broad enough to
9 cover any Accused Product alleged to infringe the Asserted Patents, either literally
10 or by application of the doctrine of equivalents, or under any theory of infringement.

11 **FOURTH DEFENSE**
12 **(Failure to State A Claim Upon Which Relief Can Be Granted)**

13 8. Edwards's Complaint fails to state a claim upon which relief can be
14 granted.
15

16 **FIFTH DEFENSE**
17 **(Equitable Defenses)**

18 9. Edwards's attempted enforcement of the Asserted Patents against
19 Abbott is barred by one or more of the equitable doctrines of estoppel, acquiescence,
20 waiver, and unclean hands.

21 **SIXTH DEFENSE**
22 **(Limitations on Damages)**

23 10. Edwards is precluded from seeking recovery for any of Abbott's
24 allegedly infringing acts occurring more than six years before the filing of the
25 Complaint, or after the expiration of the Asserted Patents. Edwards's claims for
26 damages are statutorily limited or barred by 35 U.S.C. § 286.

27 11. Edwards's claims for relief are limited by 35 U.S.C. § 271(e).
28

SEVENTH DEFENSE
(No Injunctive Relief)

12. Edwards is not entitled to injunctive relief as it has not requested such relief and has, at a minimum, an adequate remedy at law for the alleged infringement and no irreparable injury.

EIGHTH DEFENSE
(No Willfulness)

13. Edwards is barred from seeking and/or obtaining a finding of willfulness or receiving enhanced damages because Edwards has failed to allege Abbott engaged in any willful infringement or reprehensible conduct and Abbott has engaged in no such conduct, which is a prerequisite for a finding of willfulness and an award of enhanced damages.

NINTH DEFENSE
(Attorney's Fees)

14. Edwards has failed to state facts sufficient to support an award of attorney's fees.

TENTH DEFENSE
(Limitations on Costs)

15. To the extent that Edwards prevails on any of its allegations, its demand for costs is limited or barred pursuant to 35 U.S.C. § 288 because claims of the Asserted Patents are invalid.

ELEVENTH DEFENSE
(Other Defenses)

16. Abbott reserves the right to supplement or amend this Answer and reserves all defenses set out in Rule 8(c) of the Federal Rules of Civil Procedure, the

Patent Laws of the United States and any other defenses, at law or in equity, which become applicable during the course of discovery or otherwise in the course of litigation.

X. ABBOTT'S COUNTERCLAIMS

1. Abbott's Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. The Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338.

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

4. Counterclaim-Plaintiff Abbott Cardiovascular Systems, Inc. is a corporation organized and existing under the laws of the State of California and has its principal place of business at 3200 Lakeside Drive, Santa Clara, California.

5. Counterclaim-Defendant Edwards Lifesciences Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at One Edwards Way, Irvine, California. Edwards Lifesciences Corp. is subject to jurisdiction of this Court, *inter alia*, by virtue of invoking the jurisdiction of this Court by filing this action.

6. Upon information and belief, Counterclaim-Defendant Edwards Lifesciences LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at One Edwards Way, Irvine, California. Edwards Lifesciences LLC is subject to jurisdiction of this Court, *inter alia*, by virtue of invoking the jurisdiction of this Court by filing this action.

**COUNT I: DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE '767 PATENT**

7. Abbott incorporates by reference the allegations made in Abbott's Defenses and in Paragraphs 1-6 of the Counterclaims above.

8. An actual controversy exists between Abbott and Edwards Lifesciences Corp. and Edwards Lifesciences LLC (collectively, "Edwards") over the alleged infringement of at least one claim of the '767 Patent. Edwards holds itself out as the owner of the '767 Patent. Edwards has filed suit against Abbott alleging that the manufacture, sale, offer for sale, and/or importation of mitral valve repair devices sold under the names MitraClip, MitraClip NT, MitraClip NTR, and MitraClip XTR (collectively, the "Accused Products") in the United States infringes at least claim 14 of the '767 Patent in violation of 35 U.S.C. § 271(a).

9. The manufacture, sale, offer for sale, and/or importation of the Accused Products in the United States does not infringe the '767 Patent in violation of 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. Abbott hereby seeks a declaration that the manufacture, sale, offer for sale, and/or importation of the Accused Products in the United States does not infringe the '767 Patent.

10. Edwards has also alleged that Abbott has infringed at least claim 14 of the '767 Patent by supplying or causing to be supplied from the United States all or a substantial portion of the components of the Accused Products in a manner that would infringe if the combination occurred within the United States in violation of 35 U.S.C. § 271(f)(1).

11. Abbott hereby seeks a declaration that it has not infringed the '767 Patent in violation of 35 U.S.C. § 271(f)(1).

12. Edwards has further alleged that Abbott has infringed at least claim 14 of the '767 Patent by supplying components of the Accused Products in a manner that would infringe if the combination occurred within the United States in violation

1 of 35 U.S.C. § 271(f)(2).

2 13. Abbott hereby seeks a declaration that it has not infringed the '767
3 Patent in violation of 35 U.S.C. § 271(f)(2).

4 14. Abbott has not infringed and is not infringing any valid claim of the
5 '767 Patent, directly, indirectly, by inducement, contributorily, literally, under the
6 doctrine of equivalents, or in any other manner. A judicial declaration is necessary
7 and appropriate so that Abbott may ascertain its rights regarding the '767 Patent.

8 **COUNT II: DECLARATORY JUDGMENT OF**
9 **INVALIDITY OF THE '767 PATENT**

10 15. Abbott incorporates by reference the allegations in Abbott's Defenses
11 and in Paragraphs 1-14 of the Counterclaims above.

12 16. An actual controversy exists between Abbott and Edwards over the
13 invalidity of the '767 Patent. Edwards has filed suit against Abbott alleging that the
14 manufacture, sale, offer for sale, and/or importation of the Accused Products in the
15 United States infringes at least claim 14 of the '767 Patent in violation of 35 U.S.C.
16 § 271(a). Edwards has also alleged that Abbott has infringed at least claim 14 of the
17 '767 Patent by supplying or causing to be supplied from the United States all or a
18 substantial portion of the components of the Accused Products in a manner that
19 would infringe if the combination occurred within the United States in violation of
20 35 U.S.C. § 271(f)(1). Edwards has further alleged that Abbott has infringed at least
21 claim 14 of the '767 Patent by supplying components of the Accused Products in a
22 manner that would infringe if the combination occurred within the United States in
23 violation of 35 U.S.C. § 271(f)(2).

24 17. All claims of the '767 Patent are invalid because they fail to comply
25 with one or more requirements of United States Code Title 35, including, without
26 limitation, one or more requirements of 35 U.S.C. §§ 102, 103 and/or 112. By way
27 of example only, at least claim 14 of the '767 Patent is invalid as anticipated by
28

1 and/or obvious over at least U.S. Patent No. 6,629,534 (“St. Goar”) and/or WO
 2 99/00059 (“Oz”). Abbott expressly reserves all rights to identify and assert
 3 additional invalidity positions in this case.

4 18. Abbott hereby seeks a declaration that the claims of the ’767 Patent are
 5 invalid.

6 **COUNT III: DECLARATORY JUDGMENT OF**
 7 **NON-INFRINGEMENT OF THE ’669 PATENT**

8 19. Abbott incorporates by reference the allegations made in Abbott’s
 9 Defenses and in Paragraphs 1-18 of the Counterclaims above.

10 20. An actual controversy exists between Abbott and Edwards over the
 11 alleged infringement of at least one claim of the ’669 Patent. Edwards holds itself
 12 out as the owner of the ’669 Patent. Edwards has filed suit against Abbott alleging
 13 that Abbott has induced infringement and/or contributed to the infringement of at
 14 least claim 1 of the ’669 Patent in violation of 35 U.S.C. §§ 271(b) and 271(c).

15 21. Abbott hereby seeks a declaration that it has not induced infringement
 16 and/or contributed to the infringement of the ’669 Patent in violation of 35 U.S.C.
 17 §§ 271(b) or 271(c).

18 22. Abbott has not infringed and is not infringing any valid claim of the
 19 ’669 Patent, directly, indirectly, by inducement, contributorily, literally, under the
 20 doctrine of equivalents, or in any other manner. A judicial declaration is necessary
 21 and appropriate so that Abbott may ascertain its rights regarding the ’669 Patent.

22 **COUNT IV: DECLARATORY JUDGMENT OF**
 23 **INVALIDITY OF THE ’669 PATENT**

24 23. Abbott incorporates by reference the allegations made in Abbott’s
 25 Defenses and in Paragraphs 1-22 of the Counterclaims above.

26 24. An actual controversy exists between Abbott and Edwards over the
 27
 28

1 invalidity of the '669 Patent. Edwards has filed suit against Abbott alleging that
 2 Abbott has induced infringement and/or contributed to the infringement of at least
 3 claim 1 of the '669 Patent in violation of 35 U.S.C. §§ 271(b) and 271(c).

4 25. All claims of the '669 Patent are invalid because they fail to comply
 5 with one or more requirements of United States Code Title 35, including, without
 6 limitation, one or more requirements of 35 U.S.C. §§ 102, 103 and/or 112. By way
 7 of example only, at least claim 1 of the '669 Patent is invalid as anticipated by and/or
 8 obvious over at least St. Goar and/or Oz. Abbott expressly reserves all rights to
 9 identify and assert additional invalidity positions in this case.

10 26. Abbott hereby seeks a declaration that the claims of the '669 Patent are
 11 invalid.

12 **COUNT V: DECLARATORY JUDGMENT OF**
 13 **NON-INFRINGEMENT OF THE '313 PATENT**

14 27. Abbott incorporates by reference the allegations made in Abbott's
 15 Defenses and in Paragraphs 1-26 of the Counterclaims above.

16 28. An actual controversy exists between Abbott and Edwards over the
 17 alleged infringement of at least one claim of the '313 Patent. Edwards holds itself
 18 out as the owner of the '313 Patent. Edwards has filed suit against Abbott alleging
 19 that the manufacture, sale, offer for sale, and/or importation of the Accused Products
 20 in the United States infringes at least claim 1 of the '313 Patent in violation of 35
 21 U.S.C. § 271(a).

22 29. The manufacture, sale, offer for sale, and/or importation of the Accused
 23 Products in the United States does not infringe the '313 Patent in violation of 35
 24 U.S.C. § 271(a), either literally or under the doctrine of equivalents. Abbott hereby
 25 seeks a declaration that the manufacture, sale, offer for sale, and/or importation of
 26 the Accused Products in the United States does not infringe the '313 Patent.

27 30. Edwards has also alleged that Abbott has infringed at least claim 1 of
 28

1 the '313 Patent by supplying or causing to be supplied from the United States all or
 2 a substantial portion of the components of the Accused Products in a manner that
 3 would infringe if the combination occurred within the United States in violation of
 4 35 U.S.C. § 271(f)(1).

5 31. Abbott hereby seeks a declaration that it has not infringed the '313
 6 Patent in violation of 35 U.S.C. § 271(f)(1).

7 32. Edwards has further alleged that Abbott has infringed at least claim 1
 8 of the '313 Patent by supplying components of the Accused Products in a manner
 9 that would infringe if the combination occurred within the United States in violation
 10 of 35 U.S.C. § 271(f)(2).

11 33. Abbott hereby seeks a declaration that it has not infringed the '313
 12 Patent in violation of 35 U.S.C. § 271(f)(2).

13 34. Abbott has not infringed and is not infringing any valid claim of the
 14 '313 Patent, directly, indirectly, by inducement, contributorily, literally, under the
 15 doctrine of equivalents, or in any other manner. A judicial declaration is necessary
 16 and appropriate so that Abbott may ascertain its rights regarding the '313 Patent.

17 **COUNT VI: DECLARATORY JUDGMENT OF**
 18 **INVALIDITY OF THE '313 PATENT**

19 35. Abbott incorporates by reference the allegations made in Abbott's
 20 Defenses and in Paragraphs 1-34 of the Counterclaims above.

21 36. An actual controversy exists between Abbott and Edwards over the
 22 invalidity of the '313 Patent. Edwards has filed suit against Abbott alleging that the
 23 manufacture, sale, offer for sale, and/or importation of the Accused Products in the
 24 United States infringes at least claim 1 of the '313 Patent in violation of 35 U.S.C.
 25 § 271(a). Edwards has also alleged that Abbott has infringed at least claim 1 of the
 26 '313 Patent by supplying or causing to be supplied from the United States all or a
 27 substantial portion of the components of the Accused Products in a manner that
 28

1 would infringe if the combination occurred within the United States in violation of
 2 35 U.S.C. § 271(f)(1). Edwards has further alleged that Abbott has infringed at least
 3 claim 1 of the '313 Patent by supplying components of the Accused Products in a
 4 manner that would infringe if the combination occurred within the United States in
 5 violation of 35 U.S.C. § 271(f)(2).

6 37. All claims of the '313 Patent are invalid because they fail to comply
 7 with one or more requirements of United States Code Title 35, including, without
 8 limitation, one or more requirements of 35 U.S.C. §§ 102, 103 and/or 112. By way
 9 of example only, at least claim 1 of the '313 Patent is invalid as anticipated by and/or
 10 obvious over at least St. Goar and/or Oz. Abbott expressly reserves all rights to
 11 identify and assert additional invalidity positions in this case.

12 38. Abbott hereby seeks a declaration that the claims of the '313 Patent are
 13 invalid.

14 **PRAYER FOR RELIEF**

15 WHEREFORE, Abbott requests the following relief:

16 A. That the Court enter judgment against Edwards and in favor of
 17 Abbott on the claims set forth in Edwards's Complaint and that each claim be
 18 dismissed with prejudice;

19 B. That the Court enter judgment that Abbott has not and does not
 20 infringe any valid claim of the Asserted Patents in violation of 35 U.S.C. §§ 271(a),
 21 271(b), 271(c), 271(f)(1), and/or 271(f)(2), or any other theory of infringement;

22 C. That the Court enter judgment that the Asserted Patents are
 23 invalid;

24 D. That the Court determine that pursuant to 35 U.S.C. § 285,
 25 Edwards's conduct in commencing and pursuing this action renders this an
 26 exceptional case and award Abbott its reasonable attorney's fees and its costs and
 27 disbursements in this action; and
 28

1 E. That the Court grant Abbott such other and further relief, in law
2 or equity, as the Court deems just and proper.

3 **JURY DEMAND**

4 Pursuant to Rule 38 of the Federal Rules of Civil Procedure and Civil L.R.
5 38-1, Abbott hereby demands a trial by jury on all issues so triable in its
6 Counterclaims.

1 Dated: March 28, 2019

Respectfully submitted,

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3
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